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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/668,789 | 09/23/2003 | Yong D. Zhao | P0010040.00/LG10126 | 4098 |
| 27581 | 7590 | 04/29/2011 | EXAMINER | |
| MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS: LC340 Legal Patents MINNEAPOLIS, MN 55432-9924 | | | ALTER, ALYSSA MARGO | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/668,789 | Applicant(s) ZHAO ET AL. | |
| | Examiner ALYSSA M. ALTER | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 26, 2011 have been fully considered but they are not persuasive.
2. The rejection set forth in the previous office action (dated 10/28/10) states “Dutcher discloses a medical electrical lead (col. 3, lines 30-35) having **a J-shape stylet wire (depicted in figure 2; col. 3, lines 44-51)** to be slideably received within the lumen of the lead (depicted in the cutaway view of figure 7)”. The only item depicted in figure 2, is the first inner portion of the improved stylet (see col. 2, lines 67-68). Therefore, the examiner clearly considers the stylet to be the first inner portion of the improved stylet. As such, the Applicant's argument that the rejection “is respectfully asserted to be deficient because it is not set forth with sufficient clarity” (see page 10 of the Remarks) is clearly false and without merit.
3. The Applicant further argues that the combination of Dutcher and Evan III “is contrary to the teaching of Dutcher. The purpose of the preformed curve in Dutcher is to hold the distal tip of the lead stationary while the screwdriver tip on the outer component of the lead is rotated. To the extent the inner portion of the Dutcher stylet would be tapered over the curved portion, it would correspondingly have a reduced ability to hold the lead tip stationary during this procedure”.
4. Additionally, the Applicant maintains “the preformed curve in Dutcher is to hold the distal tip of the lead stationary”. It is unclear where in Dutcher it states that the “preformed curve....hold the tip of the lead stationary”. Dutcher discloses the stylet

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helps navigate the vasculature or body to reach the implantation location (col. 2, lines 25-53). This is additionally disclosed in the abstract, "the distal end of the body implantable lead is located in the position desired through the use of the solid inner first portion of the stylet in which a bend or other desired shape has been introduced". As stated above, the examiner considers the first inner portion to be the stylet (figure 2).

5. Furthermore, Evans, III et al. discloses in col. 4, lines 27-53, the tapered portion provides increased flexibility. The increase in flexibility enhances navigation of the stylet. Since Dutcher uses the stylet (see figure 2) to navigate the body or vasculature to reach the implantation location and Evans, III et al. teaches a tapered portion to increase flexibility during implantation, the modification of Dutcher to include a tapered stylet as disclosed by Evans, III et al. would enhance the maneuverability of the stylet (inner portion in figure 2) in reaching the implantation location.

6. As a result, this modification is in no way contrary to the teachings in Dutcher. Therefore, the modification of Dutcher with Evans, III et al. is held to be sufficiently clear and **not** contrary to the teachings in Dutcher. Therefore the claims 1-8 and 17-23 remain rejected under Dutcher in view of Evans, III et al..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-8 and 17-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher (US 4,381,013) in view of Evans, III et al. (US 4,854,330). Dutcher discloses a medical electrical lead (col. 3, lines 30-35) having a J-shape stylet wire (depicted in figure 2; col. 3, lines 44-51) to be slideably received within the lumen of the lead (depicted in the cutaway view of figure 7).

8. As to claims 1 and 17, Dutcher discloses the curved intermediate segment in the j-shaped stylet wire (depicted in figure 2; col. 3, lines 44-51) but does not disclose "a taper zone extending within the curved intermediate segment and having a gradual decrease in diameter". Evans, III et al. discloses (col. 7, lines 49-61) a tapered portion to increase flexibility during implantation with a taper zone in a curved segment of a stylet, as depicted in figure 11b wherein the "taper zone extending within the curved intermediate segment and having a gradual decrease in diameter". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the j-shaped stylet of Dutcher with a taper zone extending within the curved intermediate segment as disclosed by Evans, III et al. in order to provide the predictable results of enhancing the maneuverability while navigating the vasculature to facilitate implantation of the medical lead.

9. Additionally as to claims 1 and 8, Dutcher depicts in the cutaway portion of figure 7, a helical fixation means (col. 2, lines 48-50) at the distal point of the lead. The

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examiner considers the fixation helix to be extendable/ retractable since it can be screwed past fixed member 11 to be disposed at the distal end of the lead (col. 3, lines 38-42).

10. As to claims 2-4 and 18-20, the stylet of Evans, III et al. as depicted in figure 11b has a “proximal region 112, an intermediate region including longitudinally attenuated section 114, and uniform section 116” (col. 7, lines 49-53). The proximal region 112 has a diameter larger than the intermediate region 114, and the intermediate region 114 has a diameter larger than the distal uniform section 116. Thus the taper zone of the modified Dutcher has “a first diameter within the substantially straight distal segment to a second diameter within the curved intermediate segment, the second diameter being greater than the first diameter”; “wherein the first diameter within the substantially straight distal segment coincides with the distal end of the stylet”. And has a “first diameter within the substantially straight proximal segment to a second diameter within the curved intermediate segment, the first diameter being greater than the second diameter”.

11. As to claims 5-7 and 21-23, the modified Dutcher discloses the device substantially as claimed but does not explicitly mention the specific degree of curvature within the curved segment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the degree of curvature to yield the predictable results of optimizing the degree of curvature to enhance maneuverability and lead implantation. Furthermore, it has been held that where the general conditions

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of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233 (see MPEP 2144.05).

Claim Objections

12. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

13. The subject matter of claim 8 has been included in entirety into independent claim 1 and thus fails to limit the parent claim. It appears that the Applicant's intent was to cancel claim 8 since page 7 of the Remarks stated that "claim 8 is cancelled". The examiner recommends the cancellation of claim 8.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alyssa M Alter/
Examiner
Art Unit 3762

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762